

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Assaf Govari Confirmation No.: 1868
Appln. No. : 10/632,147
Filed : July 31, 2003
Title : ENCAPSULATED SENSOR WITH EXTERNAL ANTENNA
Art Unit : 3762
Examiner : Nicole R. Kramer

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

i. Real Party in Interest

Biosense Webster, Inc., a California Corporation, is the real party in interest.

ii. Related Appeals and Interferences

None.

iii. Status of Claims

Claims 1-5, 8, 10-13, 18-20, 23, 26 and 27 are pending in the case. Claims 1-5, 8, 10-13, 18-20, 23, 26 and 27 have been finally rejected on September 14, 2006 and this Appeal is taken from these claims.

iv. Status of Amendments

No Amendments have been filed subsequent to the Final Rejection mailed on September 14, 2006.

v. **Summary of Claimed Subject Matter**

As fully supported in Applicant's Specification, the claimed present invention of independent claim 1 is directed to a medical device 10 for use inside a body of a mammalian subject wherein the device 10 comprises a sealed casing 20 adapted for insertion into the body of the mammalian subject. Specification Page 9, Lines 1 –6. The casing 20 has an outer surface and comprises an insulating material 22 surrounding a conductive area 24 made of an electrically-conductive material wherein the conductive area 24 is fastened and sealed to the insulation material. Specification Page 9, Lines 8 – 11. The device 10 also comprises a transmitter 28, which is adapted to generate an electrical signal and is encapsulated in the casing 20 and coupled to the conductive area 24 so that the electrically-conductive area 24 of the outer surface serves as an antenna for transmitting the signal to a receiver outside the body wherein the signal is a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations. Specification Page 9, Lines 20-28; and Page 13, Lines 25-29 as well as FIGS 1A and 1B.

Independent Claim 12 is directed toward a medical implant 10 comprising an implantable member, comprising a metallic material 24, which is adapted to be implanted in a body of a mammalian subject as shown, for example in FIGS 4A and 4B; and a signal transmission device, comprising a casing 20 having an outer surface and an insulating material 22 surrounding a conductive area 24 made of an electrically-conductive material wherein the conductive area is fastened and sealed to the insulating material 22 and a transmitter 28, which is adapted to generate an electrical signal and is encapsulated in the casing 20 and coupled to the conductive area 24 so that the electrically-conductive area of the outer surface serves as an antenna for transmitting the signal to a receiver outside the body wherein the signal is a position signal indicative of

six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations. Specification Page 9, Line 1 - 28; Page 13, Lines 25-29; and Page 14, Line 28 – Page 15, Line 8 as well as FIGS 1A, 1B, 4A and 4B.

Independent Claim 18 of Applicant's present invention is directed to a method for transmitting a signal from inside a body of a mammalian subject wherein the method comprises encapsulating an electronic device 10 comprising a transmitter 28 in a casing 20 having an outer surface and comprising an insulating material 22 surrounding a conductive area 24 made of an electrically-conductive material wherein the conductive area 24 is fastened and sealed to the insulating material 22; coupling the transmitter 28 to the conductive material 24 so that the electrically-conductive area of the outer surface serves as an antenna for the transmitter 28; inserting the casing 20 containing the device 10 into the body of the mammalian subject; and transmitting the signal from the transmitter 28 within the body via the antenna 24 to a receiver 46 outside the body (FIG. 3) wherein the signal is a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations. Specification Page 9, Line 1 - 28; Page 13, Lines 25-29; and Page 14, Line 28 – Page 15, Line 8 as well as FIGS 1A, 1B, 2A, 2B, 3, 4A and 4B.

vi. Grounds of Rejection to be Reviewed on Appeal

1. Claims 1, 3, 5, 8 and 10 – 11 stand finally rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0095195 (Mass et al.).
2. Claims 1 - 2, 4 - 5, 8 and 10 – 11 stand finally rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,861,019 (Sun et al.).
3. Claims 1 - 3, 5, 8, 10 – 11, 18, 23 and 26 - 27 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application

Publication No. 2002/0095195 (Mass et al.) in view of U.S. Patent No. 4,846,195 (Alt) and further in view of U.S. Patent Application Publication No. 2002/0065455 (Ben-Haim et al.).

4. Claims 1 - 2, 4 - 5, 8 and 10 – 11 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,861,019 (Sun et al.) in view of U.S. Patent No. 4,846,195 (Alt) and further in view of U.S. Patent Application Publication No. 2002/0065455 (Ben-Haim et al.).
5. Claims 12 - 13 and 19 – 20 stand finally rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,447,448 (Ishikawa et al.) in view of U.S. Patent Application Publication No. 2002/0095195 (Mass et al.) or U.S. Patent No. 5,861,019 (Sun et al.) and further in view of U.S. Patent Application Publication No. 2002/0065455 (Ben-Haim et al.).

vii. Argument

1. The rejection of Claims 1, 3, 5, 8 and 10 – 11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent Application Publication No. 2002/0095195 (Mass et al.) is improper and without basis and should be overruled.

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. *In re Arkley*, 59 CCPA 804, 455 F. 2d 586, 587, 172 USPQ 524, 526 (1972). Thus, in order to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. *Soundscriber Corp. v. United States*, 360 F.2d 954,960, 148 USPQ 298, 301 (Ct. Cl. 1966).

Mass et al. teaches a split-can dipole antenna for an implantable medical device wherein this device has a housing that is “metallic” and contains therapy circuitry TC1. Paragraph No. [0013]. The medical device of Mass et al. is directed to cardiac rhythm

management and does not teach, suggest or even infer an implantable medical device having a casing comprising an insulating material surrounding a conductive area made of an electrically-conductive material and a transmitter which generates an electrical signal that is a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Moreover, Mass et al. uses schematic illustrations only and has absolutely no clear teachings as to the arrangement of its dielectric material with respect to its insulating material. Accordingly, there are no teachings in Mass et al. that could be construed as a conductive area fastened and sealed to insulation material of a casing such as distinctly claimed by Applicant's claimed invention of Claim 1.

Furthermore, Mass et al. does not teach or suggest a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information.

It is important to note that Examiner's reading of Applicant's Claim 1 is clearly erroneous in that there is no limitation in Applicant's Claim 1 that either specifically states or even infers that a certain type of signal *may* be transmitted by its transmitter. See Examiner's remarks on Page 3 of the Final Rejection dated September 14, 2006. On the contrary, Applicant's Claim 1 positively recites that its signal transmitted by its transmitter (through the conductive area which serves as an antenna) is "a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations."

Thus, it is clear that Mass et al. fails to disclose material elements recited in Applicant's Claim 1 and could never anticipate this claim due to the limited teachings

found in Mass et al.

Additionally, with respect to the Examiner's alternative obviousness rejection based on Mass et al., it is well established case law that a claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Thus, one can easily ascertain that there are significant differences between the teachings of Mass et al. and the Applicant's claimed invention of Claim 1 especially since this reference fails to teach or suggest the combination of novel features, for example, a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention.

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As taught in Par No. [0013] of Mass et al., its device has a housing that is metallic, i.e. the housing itself is conductive, unlike the casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material of Applicant's claimed present invention of Claim 1. Thus, one of ordinary skill in the implantable device and surgical navigation field would be entirely discouraged from following the path set out in the teachings of Mass et al. And, it is clear that this reference actually teaches away from Applicant's claimed present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260,

1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Not only does the Mass et al. reference set forth teachings that are completely divergent from the Applicant's claimed invention (as addressed previously above), but, there is clearly no motivation to modify the metallic casing medical device in an effort to arrive at a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention. This reference simply does not address in any manner the combination of novel features found with the Applicant's claimed present invention.

Accordingly, since Mass et al. fails to show any teaching or motivation to modify in the manner suggested by the Examiner, especially in a manner that could ever arrive at the

Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and is a classic example of hindsight.

Furthermore, as is well established, prior art patents can only be used for what they clearly disclose or suggest. *In re Randal and Redford*, 425 F. 2d 1268, 165 USPQ 586, 588 (C.C.P.A. 1970). And, as set forth in *In re Randal and Redford*, it is clearly improper to use a patent as a reference for modifying its structure in a manner in which the prior art references do not suggest. Thus, just because Mass et al. generally discloses the an implantable medical device as a split-can dipole antenna, it does not mean that unreasonable license should be taken with the teachings of this reference as proposed by the Examiner, i.e. an unreasonable attempt to modify this teaching in an effort to arrive at the Applicant's claimed present invention, especially when there is absolutely no indication in the limited teachings of Mass et al. that such a modification (as suggested by the Examiner) could ever be feasible or even desirable.

2. The rejection of Claims 1 - 2, 4 - 5, 8 and 10 – 11 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,861,019 (Sun et al.) is improper and without basis and should be overruled.

Rejections under 35 USC §102 are proper only when the claimed subject matter is identically disclosed or described in the prior art. *In re Arkley*, 59 CCPA 804, 455 F. 2d 586, 587, 172 USPQ 524, 526 (1972). Thus, in order to constitute an anticipation, all material elements recited in a claim must be found in one unit of prior art. *Soundscriber Corp. v. United States*, 360 F.2d 954,960, 148 USPQ 298, 301 (Ct. Cl. 1966).

Sun et al. is directed toward an implantable medical device microstrip telemetry antenna. The implantable medical device described in this reference is for use with a pacemaker implantable pulse generator. Sun et al. specifically teaches that its patch antenna is deposited on or embedded into the external surface of its IPG. See Col. 10, Lines 62 – 65.

Sun et al. certainly does not teach a conductive area that is fastened and sealed to insulation material of a casing of a medical device for use inside a body of a mammalian. Moreover, Sun et al. does not in any way teach, suggest or even infer a transmitter coupled to a conductive area which generates an electrical signal which is a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

It is important to note that Examiner's reading of Applicant's Claim 1 is clearly erroneous in that there is no limitation in Applicant's Claim 1 that either specifically states or even infers that a certain type of signal *may* be transmitted by its transmitter. See Examiner's remarks on Page 5 (second paragraph) of the Final Rejection dated September 14, 2006. On the contrary, Applicant's Claim 1 positively recites that its signal transmitted by its transmitter (through the conductive area which serves as an antenna) is "a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations."

Thus, it is clear that Sun et al. fails to disclose material elements recited in Applicant's Claim 1 and could never anticipate this claim due to the limited teachings found in Sun et al.

Additionally, with respect to the Examiner's alternative obviousness rejection based on Sun et al., it is well established case law that a claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Thus, one can easily ascertain that there are significant differences between the teachings of Sun et al. and the Applicant's claimed invention of Claim 1 especially since this reference fails to teach or suggest the combination of novel features, for example, a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention.

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As taught in Co. 10, Lines 62 – 65 of Sun et al., its IPG device uses a patch antenna that is either deposited on or embedded into the external surface of its IPG, unlike the casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material of Applicant's claimed present invention of Claim 1. Thus, one of ordinary skill in the implantable device and surgical navigation field would be entirely discouraged from following the path set out in the teachings of Sun et al. And, it is clear that this reference actually teaches away from Applicant's claimed present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (BPAI 1985).

Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774

F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Not only does the Sun et al. reference set forth teachings that are completely divergent from the Applicant's claimed invention (as addressed previously above), but, there is clearly no motivation to modify the patch antenna/IPG device combination in an effort to arrive at a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention. This reference simply does not address in any manner the combination of novel features found with the Applicant's claimed present invention.

Accordingly, since Sun et al. fails to show any teaching or motivation to modify in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and is a classic example of hindsight.

Furthermore, as is well established, prior art patents can only be used for what they clearly disclose or suggest. *In re Randal and Redford*, 425 F. 2d 1268, 165 USPQ 586, 588 (C.C.P.A. 1970). And, as set forth in *In re Randal and Redford*, it is clearly improper to use a patent as a reference for modifying its structure in a manner in which the prior art references do not suggest. Thus, just because Sun et al. generally discloses an implantable medical device (IPG) with a patch antenna, it does not mean that unreasonable license should be taken with the teachings of this reference as proposed by the Examiner, i.e. an unreasonable attempt to modify this teaching in an effort to arrive at the Applicant's claimed present invention, especially when there is absolutely no indication in the limited teachings

of Sun et al. that such a modification (as suggested by the Examiner) could ever be feasible or even desirable.

3. The rejection of Claims 1 - 3, 5, 8,10 – 11, 18, 23 and 26 - 27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. 2002/0095195 (Mass et al.) in view of U.S. Patent No. 4,846,195 (Alt) and further in view of U.S. Patent Application Publication No. 2002/0065455 (Ben-Haim et al.) is improper and without basis and should be overruled.

Mass et al. teaches a split-can dipole antenna for an implantable medical device wherein this device has a housing that is “metallic” and contains therapy circuitry TC1. Paragraph No. [0013]. The medical device of Mass et al. is directed to cardiac rhythm management and does not teach, suggest or even infer an implantable medical device having a casing comprising an insulating material surrounding a conductive area made of an electrically-conductive material and a transmitter which generates an electrical signal that is a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Moreover, Mass et al. uses schematic illustrations only and has absolutely no clear teachings as to the arrangement of its dielectric material with respect to its insulating material. Accordingly, there are no teachings in Mass et al. that could be construed as a conductive area fastened and sealed to insulation material of a casing such as distinctly claimed by Applicant’s claimed invention of Claim 1.

Furthermore, the Examiner specifically admits that that Mass et al. fails to teach a position sensor, let alone, any ability to transmit a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations such as distinctly claimed by Applicant’s claimed invention of Claim 1.

Alt teaches an implantable position and motion sensor using a chamber with a mercury ball and a plurality of electrodes wherein this arrangement is used to determine

orientation of the sensor. This is especially useful for pacemaker devices. It is important to note that this arrangement can only detect orientation and does not generate a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Ben-Haim et al. teaches medical diagnosis, treatment and imaging system for determining three location coordinates and three orientation coordinates of an invasive medical instrument. This reference does not in any way address, suggest or even infer a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information.

It is well-established case law that a claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of non-obviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Thus, one can easily ascertain that there are significant differences between the teachings of Mass et al., Alt and Ben-Haim et al. and the Applicant's claimed invention of Claim 1 especially since these references fail to teach or suggest the combination of novel features, for example, a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position

signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention.

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As taught in Par No. [0013] of Mass et al., its device has a housing that is metallic, i.e. the housing itself is conductive, unlike the casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material of Applicant's claimed present invention of Claim 1. Thus, one of ordinary skill in the implantable device and surgical navigation field would be entirely discouraged from following the path set out in the teachings of Mass et al. And, it is clear that this reference actually teaches away from Applicant's claimed present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Not only does the Mass et al. reference set forth teachings that are completely divergent from the Applicant's claimed invention (as addressed previously above), but, there is clearly no motivation to modify or combine the metallic casing medical device of Mass et al., with the implantable position and motion sensor using mercury ball and chamber for determining only orientations as taught by Alt with the invasive medical

instrument with three location coordinates and three orientation coordinate determination as taught by Ben-Haim et al. in an effort to arrive at a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention. These references simply do not address in any manner the combination of novel features found with the Applicant's claimed present invention.

Accordingly, since Mass et al., Alt or Ben-Haim et al. fail to show any teaching or motivation to modify or combine in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and is a classic example of hindsight.

4. The rejection of Claims 1 - 2, 4 - 5, 8 and 10 – 11 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,861,019 (Sun et al.) in view of U.S. Patent No. 4,846,195 (Alt) and further in view of U.S. Patent Application Publication No. 2002/0065455 (Ben-Haim et al.) is improper and without basis and should be overruled.

Sun et al. is directed toward an implantable medical device microstrip telemetry antenna. The implantable medical device described in this reference is for use with a pacemaker implantable pulse generator. This reference does not teach, suggest or even infer a transmitter which generates an electrical signal which is a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Alt teaches an implantable position and motion sensor using a chamber with a mercury ball and a plurality of electrodes wherein this arrangement is used to determine orientation of the sensor. This is especially useful for pacemaker devices. It is important to

note that this arrangement can only detect orientation and does not generate a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Ben-Haim et al. teaches medical diagnosis, treatment and imaging system for determining three location coordinates and three orientation coordinates of an invasive medical instrument. This reference does not in any way address, suggest or even infer a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information.

It is well-established case law that a claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of non-obviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Thus, one can easily ascertain that there are significant differences between the teachings of Sun et al., Alt and Ben-Haim and the Applicant's claimed invention of Claim 1 especially since these references fail to teach or suggest the combination of novel features, for example, a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position

signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention.

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As taught in Co. 10, Lines 62 – 65 of Sun et al., its IPG device uses a patch antenna that is either deposited on or embedded into the external surface of its IPG, unlike the casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material of Applicant's claimed present invention of Claim 1. Thus, one of ordinary skill in the implantable device and surgical navigation field would be entirely discouraged from following the path set out in the teachings of Sun et al. And, it is clear that this reference actually teaches away from Applicant's claimed present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight

syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.¹

Not only does the Sun et al. reference set forth teachings that are completely divergent from the Applicant's claimed invention (as addressed previously above), but, there is clearly no motivation to modify or combine the patch antenna/IPG device

combination of Sun et al., with the implantable position and motion sensor using mercury ball and chamber for determining only orientations as taught by Alt with the invasive medical instrument with three location coordinates and three orientation coordinate determination as taught by Ben-Haim et al. in an effort to arrive at a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention. These references simply do not address in any manner the combination of novel features found with the Applicant's claimed present invention.

Accordingly, since neither Sun et al., Alt nor Ben-Haim et al. fail to show any teaching or motivation to modify or combine in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and is a classic example of hindsight.

Furthermore, as is well established, prior art patents can only be used for what they clearly disclose or suggest. *In re Randal and Redford*, 425 F. 2d 1268, 165 USPQ 586, 588 (C.C.P.A. 1970). And, as set forth in *In re Randal and Redford*, it is clearly improper to use a patent as a reference for modifying its structure in a manner in which the prior art references do not suggest. Thus, just because Sun et al. generally discloses an implantable medical device (IPG) with a patch antenna, it does not mean that unreasonable license should be taken with the teachings of this reference as proposed by the Examiner, i.e. an unreasonable attempt to modify this teaching in an effort to arrive at the Applicant's claimed present invention, especially when there is absolutely no indication in the limited teachings of Sun et al. that such a modification (as suggested by the Examiner) could ever be feasible or even desirable.

5. The rejection of Claims 12 - 13 and 19 – 20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,447,448 (Ishikawa et al.) in view of U.S. Patent Application Publication No. 2002/0095195 (Mass et al.) or U.S. Patent No. 5,861,019 (Sun et al.) and further in view of U.S. Patent Application Publication No. 2002/0065455 (Ben-Haim et al.) is improper and without basis and should be overruled.

Ishikawa et al. is directed toward miniature implanted orthopedic sensors that are substantially spherical semiconductor balls implanted in orthopedic structures for functions such as sensing and/or stimulation. Remote energizing and interrogation is briefly addressed on Column 6, Lines 30-44. Ishikawa et al. clearly describes that its semiconductor balls have an inductance coil 120 formed of wire 128 which is wound on the surface of a substrate 142 around the semiconductor ball 110 forming non-conductive spaces 124 and 126 between the windings 129. This arrangement is completely different than the insulating material surrounding a conductive area made of an electrically-conductive material such as found with the medical device/implant of Applicant's claimed present invention.

Additionally, although Ishikawa et al. generally describes using its transponders as position sensors, there is absolutely no teaching, suggestion or even inference that the signals generated can be indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations such as distinctly claimed by Applicant's claimed present invention as amended.

Mass et al. teaches a split-can dipole antenna for an implantable medical device wherein this device has a housing that is "metallic" and contains therapy circuitry TC1. Paragraph No. [0013]. The medical device of Mass et al. is directed to cardiac rhythm management and does not teach, suggest or even infer an implantable medical device having a casing comprising an insulating material surrounding a conductive area made of an electrically-conductive material and a transmitter which generates an electrical signal that is a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Sun et al. is directed toward an implantable medical device microstrip telemetry antenna. The implantable medical device described in this reference is for use with a pacemaker implantable pulse generator. This reference does not teach, suggest or even infer a transmitter which generates an electrical signal which is a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Ben-Haim et al. teaches medical diagnosis, treatment and imaging system for determining three location coordinates and three orientation coordinates of an invasive medical instrument. This reference does not in any way address, suggest or even infer a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information.

It is well established case law that a claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (Supp. 1998); *see Graham v. John Deere Co.*, 383 U.S. 1, 14, 148 USPQ 459, 465 (1966). The ultimate determination of whether an invention is or is not obvious is a legal conclusion based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of non-obviousness. *See Graham*, 383 U.S. at 17-18, 148 USPQ at 467; *Miles Labs, Inc., Inc. v. Shandon Inc.*, 997 F.2d 870, 877, 27 USPQ2d 1123, 1128 (Fed. Cir. 1993).

Thus, one can easily ascertain that there are significant differences between the teachings of Ishikawa et al., Sun et al., Mass et al. and Ben-Haim and the Applicant's claimed invention of Claim 12 especially since these references fail to teach or suggest the combination of novel features, for example, a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is

fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention.

Moreover, as set forth in *In re Gurley*, 27 F.3d 551; 31 USPQ 2d 1130 (Fed. Cir. 1994):

A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be in a direction divergent from the path that was taken by Applicant.

As taught in Ishikawa et al., its implantable orthopedic ball uses inductance coil 120 formed of wire 128 which is wound on the surface of a substrate 142 around the semiconductor ball 110 forming non-conductive spaces 124 and 126 between the windings 129. This arrangement is completely different than the casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material of Applicant's claimed present invention of Claim 12. Thus, one of ordinary skill in the implantable device and surgical navigation field would be entirely discouraged from following the path set out in the teachings of Ishikawa et al. And, it is clear that this reference actually teaches away from Applicant's claimed present invention.

In establishing a basis for denying patentability of an invention, the initial burden rests with the Examiner. *In re Piasecki*, 745 F.2d 1468; 223 USPQ 785 (Fed. Cir. 1984). Thus, it is incumbent upon the Examiner to provide a reason why of ordinary skill in the art would have been led to modify a prior art reference or to combine teachings in order to arrive at the claimed invention. *Ex Parte Clapp*, 227 USPQ 972 (BPAI 1985). Moreover, this reason must stem from some teaching, suggestion or inference in the prior art or knowledge generally available and not from the Applicant's disclosure. *Uniroyal, Inc., v. Rudkin-Wiley Corp.*, 837 F.2d 1044; 5 USPQ 2d 1434 (Fed. Cir. 1988). As stated

in *W.L. Gore and Associates, Inc., v. Garlock, Inc.*, 721 F.2d 1540; 220 USPQ 303 (Fed. Cir. 1983):

[t]o imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

The Federal Circuit's case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically . . . the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (Examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed. Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). *See also Graham*, 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. *See, e.g., Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, it appears that the Examiner has fallen into the hindsight trap.'

Not only does the Ishikawa et al., Mass et al., Sun et al. and Ben-Haim et al. references set forth teachings that are completely divergent from the Applicant's claimed invention (as addressed previously above), but, there is clearly no motivation to modify or combine the wound coil semiconductor orthopedic ball of Ishikawa et al. with the patch antenna/IPG device combination of Sun et al., or with the split can dipole antenna of Mass et al. with the invasive medical instrument with three location coordinates and three orientation coordinate determination as taught by Ben-Haim et al. in an effort to arrive at a medical device comprising a casing having insulating material surrounding a conductive area wherein the conductive area is fastened and sealed to the insulation material and a transmitter encapsulated in the casing and coupled to the conductive area so that the conductive area operates as an antenna for transmitting a position signal which is indicative of six-dimensional position and orientation information such as distinctly claimed by Applicant's claimed present invention. These references simply do not address in any manner the combination of novel features found with the Applicant's claimed present invention.

Accordingly, since neither Ishikawa et al., Mass et al., Sun et al., nor Ben-Haim et al. fail to show any teaching or motivation to modify or combine in the manner suggested by the Examiner, especially in a manner that could ever arrive at the Applicant's claimed present invention, there is no doubt that Applicant's own disclosure is being improperly used as a blue print and is a classic example of hindsight.

Therefore, based on the reasons outlined above, it is clear that these anticipation and/or obviousness rejections are without merit and should be overruled.

Respectfully submitted,

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viii. Claims Appendix

- Claim 1. A medical device for use inside a body of a mammalian subject, the device comprising:
a casing adapted for insertion into the body of the mammalian subject, the casing having an outer surface and comprising an insulating material surrounding a conductive area made of an electrically-conductive material, the conductive area fastened and sealed to the insulation material; and
a transmitter, which is adapted to generate an electrical signal and is encapsulated in the casing and coupled to the conductive area so that the electrically-conductive area of the outer surface serves as an antenna for transmitting the signal to a receiver outside the body, the signal being a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.
- Claim 2. The device according to claim 1, wherein the insulating material comprises at least one of a ceramic material and a plastic material.
- Claim 3. The device according to claim 1, wherein the casing has an inner surface, and wherein the electrically-conductive material is arranged to fill an entire thickness of the casing between the inner surface and the electrically-conductive area of the outer surface.
- Claim 4. The device according to claim 1, wherein the conductive material is arranged in a layer overlying the insulating material in the electrically-conductive area.

- Claim 5. The device according to claim 1, wherein the electrically-conductive area is configured to contact a metal implant within the body of the mammalian subject while transmitting the signal.
- Claim 8. The device according to claim 1, and comprising a sensor, which is encapsulated within the casing and is adapted to sense a parameter associated with a location of the device within the body, wherein the sensor is coupled to the transmitter so that the signal generated by the transmitter is indicative of the sensed parameter.
- Claim10. The device according to claim 8, wherein the parameter comprises a physiological parameter.
- Claim11. The device according to claim 10, wherein the sensor comprises at least one of a pressure sensor, a temperature sensor, a flow sensor, a chemical sensor, an electrical sensor and an optical sensor.
- Claim 12. A medical implant, comprising:
an implantable member, comprising a metallic material, which is adapted to be implanted in a body of a mammalian subject; and
a signal transmission device, comprising:
a casing having an outer surface and comprising an insulating material surrounding a conductive area made of an electrically-conductive material, the conductive area fastened and sealed to the insulating material; and
a transmitter, which is adapted to generate an electrical signal and is encapsulated in the casing and coupled to the conductive area so that the electrically-conductive area of the outer surface serves as an antenna for transmitting the signal to a receiver outside the

body, the signal being a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Claim 13. The implant according to claim 12, wherein the implantable member comprises an implantable orthopedic device.

Claim 18. A method for transmitting a signal from inside a body of a mammalian subject, the method comprising:
encapsulating an electronic device comprising a transmitter in a casing having an outer surface and comprising an insulating material surrounding a conductive area made of an electrically-conductive material, the conductive area fastened and sealed to the insulating material;
coupling the transmitter to the conductive material so that the electrically-conductive area of the outer surface serves as an antenna for the transmitter;
inserting the casing containing the device into the body of the mammalian subject; and
transmitting the signal from the transmitter within the body via the antenna to a receiver outside the body, the signal being a position signal indicative of six-dimensional position and orientation including X, Y, Z directions and pitch, yaw and roll orientations.

Claim 19. The method according to claim 18, wherein inserting the casing comprises making contact between the electrically-conductive area and a metal implant that is placed within the body of the mammalian subject, so as to increase a gain of the antenna in transmitting the signal.

- Claim 20. The method according to claim 19, wherein the metal implant comprises an orthopedic implant, and wherein inserting the casing comprises fixing the orthopedic implant to a bone in the body.
- Claim 23. The method according to claim 18, wherein transmitting the signal comprises sensing a parameter associated with a location of the device within the body, wherein the transmitted signal is indicative of the sensed parameter.
- Claim 26. The method according to claim 23, wherein sensing the parameter comprises sensing a physiological parameter with respect to the body.
- Claim 27. The method according to claim 26, wherein sensing the physiological parameter comprises sensing at least one of a pressure, a temperature, a flow characteristic, a chemical characteristic, an electrical characteristic and an optical characteristic.

ix. **Evidence Appendix**

Not Applicable.

x. **Related Proceedings Appendix**

Not Applicable.